

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE COLUMBIA UNIVERSITY
PATENT LITIGATION

MDL No. 1592 (MLW)

This Document Relates To All Actions

**COLUMBIA UNIVERSITY'S SUPPLEMENTAL MEMORANDUM REGARDING
THE IMPLICATIONS OF PROSECUTION LACHES ALLEGATIONS ON
COLUMBIA'S MOTION TO DISMISS**

Dated: October 12, 2004

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I. PRELIMINARY STATEMENT

In its Order of October 7, 2004, the Court asked the parties to consider “whether the allegation of prosecution laches changes the analysis of *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed. Cir. 1991) with respect to the ’275 patent and *GAF Building Materials Corp. v. Elk Corp. of Dallas*, 90 F.3d 479 (Fed. Cir. 1996) with respect to the ’159 application.” The allegation of prosecution laches does not change the analysis of whether the Court has subject matter jurisdiction over plaintiffs’ declaratory relief claims. Under controlling Federal Circuit authority, Columbia’s covenant not to sue eliminates any actual case or controversy and requires the dismissal of plaintiffs’ declaratory relief claims.

The Federal Circuit has long employed a two-part test to determine whether subject matter jurisdiction exists over declaratory relief claims relating to patent rights. One part of the test looks to the patentee’s conduct: “the patent holder’s conduct must create an objectively reasonable apprehension on the part of the accused infringer that the patent holder will initiate suit if the allegedly infringing activity continues.” *Spectronics*, 940 F.2d at 634. The other part of the test looks to the accused infringer’s conduct: “the accused infringer must have actually produced or prepared to produce an allegedly infringing product.” *Id.*

Plaintiffs cannot satisfy this test. As to the ’275 patent, Columbia’s covenant not to sue eliminates any reasonable apprehension that plaintiffs will face an infringement suit—the first part of the test for justiciability. As to the reissue application and the ’159 application, there are no issued claims by which to gauge whether plaintiffs are engaging in, or preparing to engage in, infringing conduct—the second part of the test for justiciability.

Plaintiffs have argued that the Court should allow them to litigate their prosecution laches allegations with respect to the ’275 patent because a favorable ruling, they contend, will also render unenforceable any claim of any patent that may issue based upon the reissue application

or the '159 application. This argument simply ignores the well-developed body of Federal Circuit case law for determining the existence of an *actual* case or controversy sufficient to satisfy Article III. The purpose of this case law is to limit declaratory relief actions to situations where there is “a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *GAF Building*, 90 F.3d at 482 (citing *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-241 (1937)). Here, plaintiffs’ requested relief relates entirely to a hypothetical state of facts: the fate of the reissue application and the '159 application. Plaintiffs seek an advisory opinion upon which they can rely *if and when* the '275 patent ever emerges from reissue proceedings, or *if and when* a patent ever issues from the '159 application. That is not permissible under Article III.

As discussed below, it is irrelevant whether a ruling on the '275 patent would assist plaintiffs in attacking, or Columbia in upholding, any patent that may issue in the future. Under *Spectronics*, Columbia’s covenant not to sue completely eliminates subject matter jurisdiction over any dispute concerning the '275 patent, even though plaintiffs “may have some cause to fear a suit for future infringement of substantively non-identical claims after reissue[.]” 940 F.2d at 637-38. Moreover, under *GAF Building*, plaintiffs cannot establish a “substantial controversy admitting of specific relief through a decree of a conclusive character” with respect to the pending '159 application, whose claims are in flux and whose ultimate fate is unknown. 90 F.3d at 482. Columbia is not aware of a single case in which a district court exercised declaratory judgment jurisdiction to consider the validity, enforceability, or infringement of a patent application, and *every* Federal Circuit case to consider this issue has found subject matter

jurisdiction lacking in such instances. Accordingly, Columbia's motion to dismiss should be granted.

II. ARGUMENT

A. Plaintiffs' Prosecution Laches Allegations Do Not Create Subject Matter Jurisdiction Over The '275 Patent, Even Though A Reissue Application Is Pending

1. Columbia's Covenant Not To Sue Eliminates Subject Matter Jurisdiction Over Any Dispute Concerning The '275 Patent

The teaching of *Spectronics* and its progeny is that a patentee's covenant not to sue a declaratory plaintiff on any claims of an issued patent eliminates the existence of a case or controversy with respect to the validity, enforceability, or infringement of that patent. No Federal Circuit decision has ever suggested that the effectiveness of a covenant not to sue depends on the specific legal theory relied upon to attack the validity or enforceability of the patent. In fact, just the opposite is true.

As Columbia's counsel noted at the October 6 hearing, in *Intellectual Property Development, Inc. v. TCI Cablevision of Cal., Inc.*, 248 F.3d 1333 (Fed. Cir. 2001), the Federal Circuit rejected the defendants' argument that the specific legal theory under which they were attacking the patent-in-suit was relevant to determining whether the plaintiffs' covenant not to sue divested the district court of subject matter jurisdiction. Specifically, the Federal Circuit held: "It is of no consequence to the case at issue that *Super Sack* concerned a declaratory counterclaim for noninfringement and invalidity while TCI-California counterclaimed for declaratory judgment on the issues of noninfringement, invalidity, and *unenforceability*." *Id.* at 1342 n.9 (emphasis added).

This result is hardly surprising given the test for determining the existence of subject matter jurisdiction “[i]n the domain of suits for declarations of patent rights and relationships[.]” *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1058 (Fed. Cir. 1995). Under the first part of this test, the declaratory plaintiff must establish “an explicit threat or other action by the patentee, which creates a *reasonable* apprehension on the part of the declaratory plaintiff that it will face an infringement suit[.]” *Id.* (emphasis in original). A covenant not to sue, such as the one approved in *Spectronics* (and adopted by Columbia), eliminates any reasonable apprehension that the declaratory plaintiff will face an infringement suit. *Spectronics*, 940 F.2d at 638 (declaratory plaintiff “has no cause for concern that it can be held liable for practicing the invention claimed in the ’366 patent. As to that invention, Fuller is estopped by its statement of non liability, on its face and as explained by Fuller, from asserting liability for the making, selling or using of any Spectronics’ product that would infringe the claims of the ’366 patent.”).¹

¹ Counsel for Biogen and Genzyme attempted to distinguish *Spectronics* at the October 6 hearing on two principal grounds. First, counsel argued that *Spectronics* only involved a requested declaration of non-infringement, whereas the instant case also involves a requested declaration of unenforceability on the basis of prosecution laches. Ex. A to Sheasby Declaration (Tr. at 26:25-28:8). Counsel’s description of *Spectronics* is inaccurate. In that case, the plaintiff asserted “entitlement to a declaratory judgment of *invalidity or non-infringement* of the claims of the ’366 patent” 940 F.2d at 633.

Second, counsel argued that the reissue application in *Spectronics* did not have any claims at the time that the covenant was granted and, as a result, the plaintiff in that case could not have any reasonable apprehension of suit with respect to unknown claims in that application. In contrast, counsel argued, the reissue application for the ’275 patent has broad draft claims that give Biogen and Genzyme reasonable apprehension that Columbia will sue them once a reissued patent emerges from the PTO. Ex. A (Tr. at 29:11-30:5). However, the passage from *Spectronics* on which counsel relied rather clearly refers to the fact that the PTO had not yet reissued a new patent with new claims—a requirement for the litigation of a declaratory relief claim—not that the reissue application contained no proposed claims. 940 F.2d at 636 (“*Spectronics* can not demonstrate that its present activity is potentially infringing *of any patent claims*, since it is immune to suit under the claims of the ’366 patent, *and no reissue patent claims yet exist by which infringement vel non can be measured.*”) (emphasis added).

In the absence of any reasonable apprehension that it will face an infringement suit, it is impossible for the declaratory plaintiff to satisfy the first part of the Federal Circuit's test for subject matter jurisdiction, no matter what theory of invalidity or unenforceability that plaintiff would like to assert. *Super Sack*, 57 F.3d at 1059 ("Because Chase can have no reasonable apprehension that it will face an infringement suit on the '796 and '652 patents with respect to past and present products, it fails to satisfy the first part of our two-part test of justiciability.').

Here, plaintiffs have no apprehension—reasonable or otherwise—that they will ever face a suit for infringement of the '275 patent. As a result, they have no constitutional standing to attack the validity or enforceability of the '275 patent *on any ground whatsoever*. Indeed, in *Super Sack*, faced with a covenant not to sue that eliminated subject matter jurisdiction over the defendant's counterclaims "for declaratory judgments of both *noninfringement and invalidity*, the latter on anticipation and obviousness grounds," *id.* at 1055, the defendant filed a "motion to amend its pleadings to include a declaratory judgment counterclaim of *unenforceability* due to inequitable conduct," *id.* (emphasis added). The district court denied the motion to amend, *id.* at 1057, and the Federal Circuit affirmed, *id.* at 1060. The Federal Circuit concluded that "post-filing events rendered moot the controversy in this case. To proceed would have involved the court in rendering a forbidden advisory opinion." *Id.* at 1060.

In short, plaintiffs' prosecution laches claims—like plaintiffs' inequitable conduct claims—are simply another avenue of attack on the enforceability of the '275 patent. Because plaintiffs can have no reasonable apprehension of suit for infringing the '275 patent—and thus cannot meet the first part of the Federal Circuit's test for justiciability of a patent-related

declaratory relief claim—there is no subject matter jurisdiction over any claim seeking to render the '275 patent invalid or unenforceable under any legal theory.²

2. There Can Be No Actual Case Or Controversy Over The Pending Application To Reissue The '275 Patent

The plaintiff in *Spectronics* made the same argument as the plaintiffs in the case at bar: “the potential grant of a reissue patent manifestly places it at risk of further litigation on the subject matter contained in the specification of the '366 patent, which Spectronics believes will reappear in the claims of the reissue patent and form the basis for threatened or actual litigation against it.” 940 F.2d at 636. The Federal Circuit squarely rejected this argument as a basis for exercising subject matter jurisdiction over the plaintiff’s declaratory relief claims of non-infringement and invalidity. The reasoning of *Spectronics* makes clear that an allegation of prosecution laches would not alter this result.

² See also *SL Waber, Inc. v. American Power Conversion Corp.*, 135 F. Supp. 2d 521, 525 (D.N.J. 1999) (granting motion to dismiss “APC’s counterclaim for a declaratory judgment that the '991 patent is unenforceable, invalid and not infringed[,]” court concluded that Waber’s covenant not to sue “eliminates any concern APC could have about the threat of future patent infringement litigation by Waber under the '991 patent involving any past, present or future APC product. This blanket immunity from future patent litigation concerning the '991 patent renders the likelihood of such future litigation far slimmer than the ‘residual possibility of a future infringement suit based on [the alleged infringer’s] future acts’ that the court in *Super Sack* found ‘too speculative a basis for jurisdiction over [the] counterclaim for declaratory judgments of invalidity.’”) (brackets in original); *Biogen, Inc. v. Amgen, Inc.*, 913 F. Supp. 35, 38 (D. Mass. 1996) (where Biogen granted covenant not to sue on all but two claims of the '702 patent against any product currently manufactured and sold by Amgen, court granted motion to dismiss counterclaims of invalidity and unenforceability on account of inequitable conduct as to all other claims of the '702 patent, notwithstanding Amgen’s objection that Biogen “behaved improperly in obtaining and seeking to enforce certain of the '702 patent claims, and as a result is seeking to weasel out of litigation that might place its entire patent in jeopardy.”); *Level 1 Technologies, Inc. v. C.R. Bard, Inc.*, 839 F. Supp. 90, 91 (D. Mass. 1994) (where plaintiff sought declaration that the '333 patent was invalid and not infringed, court granted motion to dismiss for no reasonable apprehension of suit where defendant and inventor covenanted “that Level 1 has no current liability for infringement of patent No. '333 and that Bard and Fried will not sue Level 1 for the making, using, or selling of any existing Level 1 product based on that patent.”)

In *Spectronics*, the Federal Circuit noted that a declaratory plaintiff “must have actually produced or prepared to produce an allegedly infringing product,” in addition to having a reasonable apprehension of an infringement suit. 940 F.2d at 634. The Federal Circuit held as a matter of law that the defendant’s pending reissue application could not satisfy this part of the test for subject matter jurisdiction, “even if Spectronics had an objectively reasonable apprehension about a future suit based upon the reissue patent[.]” *Id.* at 636. As the court of appeals observed, unless and until the PTO reissues the patent, “no reissue patent claims yet exist by which infringement *vel non* can be measured.” *Id.* Accordingly, in language that unequivocally addresses the issue now under consideration by this Court, the Federal Circuit held that “*the existence of issued patent claims, presently enforceable against Spectronics, are a requisite to litigation of a declaratory judgment action.*” *Id.* (emphasis added). The Federal Circuit explained its reasoning:

Spectronics is required to demonstrate that it is engaged in potentially infringing conduct, such that it “has a true interest to be protected by the declaratory judgment.” Before a patent issues, and during the pendency of a patent application in the PTO, the courts have no claims by which to gauge an alleged infringer’s conduct.

Id. (citations omitted). Because the defendant had granted a covenant not to sue with respect to the ’366 patent, and because the PTO had not issued a new patent containing claims “by which to gauge an alleged infringer’s conduct,” *id.*, the Federal Circuit affirmed the dismissal of the plaintiff’s declaratory relief claims. *Id.* at 638.

Plaintiffs’ prosecution laches allegations do not create any basis for the Court to exercise subject matter jurisdiction over their declaratory relief claims. Irrespective of the legal doctrine upon which a declaratory plaintiff relies, there can be no subject matter jurisdiction over a

declaratory relief action concerning a pending reissue application. Rather, as the Federal Circuit held in *Spectronics*, “the existence of issued patent claims . . . are a requisite to litigation of a declaratory judgment action,” *id.* at 636, even if the declaratory plaintiff has a reasonable apprehension that it will be sued for infringement if and when the PTO issues a patent based upon a pending reissue application. In short, while there may be a dispute between plaintiffs and Columbia concerning the reissue application, it is not a cognizable dispute under Article III.

It is worth noting that Spectronics desired to continue litigating over the '366 patent for the very same reasons that plaintiffs desire to continue litigating over the '275 patent: It hoped to secure a judicial ruling on the '366 patent that could be used to attack any reissue patent that may later emerge from the PTO. On appeal to the Federal Circuit, Spectronics contended that the '366 patent was invalid because the patentee committed inequitable conduct before the PTO by “knowingly and deliberately conceal[ing] prior anticipatory art from the patent examiner.” Ex. B to Sheasby Declaration (Brief of Plaintiff-Appellant Spectronics Corp. at 4, *Spectronics Corp. v. H.B. Fuller Co., Inc.*, 940 F.2d 631 (Fed. Cir. 1991) (No. 91-1041) (“Spectronics’ App. Brief”). Spectronics argued that because “a reissue patent cannot purge inequitable conduct[,] . . . the District Court committed reversible error in dismissing this action and in failing to address the very substantial allegations of inequitable conduct.” Ex. B (Spectronics’ App. Brief at 18). In its brief, Spectronics relied upon the passage from *Hoffman-La Roche Inc. v. Lemmon Co.*, 906 F.2d 684, 688-89 (Fed Cir. 1990), where the Federal Circuit stated that, “if the District Court finds that there was inequitable conduct in the prosecution of the original patent then the reissue patent is invalid and an appropriate judgment should be entered.” Ex. B (Spectronics’ App. Brief at 36). Accordingly, Spectronics requested the Federal Circuit “to rule that where a declaratory judgment action implicates evidence of inequitable conduct in prosecution of a patent, the

District Court should retain jurisdiction since it is the only forum where such issues can be determined especially where, as here, a possibility exists that the patent holder will attempt further enforcement of the patent against the plaintiff and its customers.” Ex. B (Spectronics’ App. Brief at 20) (emphasis in original).

As is apparent from its decision, the Federal Circuit concluded that no Article III jurisdiction existed despite the fact that, according to Spectronics, there was a remedy available in the district court—a finding of inequitable conduct—that would have conclusively resolved any of Spectronics’ concerns regarding the pending reissue application. The Federal Circuit’s decision makes clear that the touchstone of Article III jurisdiction over a patent-related declaratory relief action is the presence of issued claims. Absent issued claims, any decision by a district court is simply an impermissible advisory decision with respect to a patent that has not issued, and may never issue.³

B. There Can Be No Case Or Controversy Over The Validity, Enforceability, Or Infringement Of Any “Claim” In The Pending ’159 Application

Just as plaintiffs’ prosecution laches allegations cannot create an actual case or controversy as to the reissue application, those allegations also cannot create an actual case or

³ Genentech’s counsel argued at the October 6 hearing that Columbia’s covenant was inadequate under *Spectronics* to eliminate subject matter jurisdiction because it did not cover the full scope of the invention “defined in the specification of the patent.” Ex. A (Tr. at 63:4-21). This argument betrays a fundamental misunderstanding of basic patent law: The scope of patent protection is defined by the *claims* of a patent, not the *specification*. See, e.g., *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 77 F.3d 1364, 1369 (Fed. Cir. 1996) (“The claims, however, not the specification, measure the protected patent right to exclude others.”). Indeed, the passage from *Spectronics* cited by Genentech’s counsel undermines, rather than supports, her client’s position. 940 F.3d at 637-638 (“Although Spectronics may have some cause to fear a suit for future infringement of substantively non-identical claims after reissue, it has no cause for concern that it can be held liable for practicing *the invention claimed in the ’366 patent*.”) (emphasis added).

controversy as to the '159 application. The reason is exactly the same: There is no subject matter jurisdiction under Article III with respect to disputes concerning the validity, enforceability, or infringement of "claims" in a pending patent application, irrespective of the legal theory on which a declaratory plaintiff may rely to attack the application.

The Federal Circuit's decision in *GAF Building* is controlling. There, defendant Elk received a notice of allowance from the PTO for its pending design patent application directed to a laminated asphalt roofing shingle. After paying the required issue fee, but before the patent issued, Elk sent a letter to plaintiff GAF alleging that sales of its roofing shingle "'constitute an infringement of Elk Corporation's forthcoming United States design patent'" and demanding that GAF "'cease and desist from all infringing activities with respect to this United States design patent when issued.'" 90 F.3d at 480. In response, GAF filed an action alleging that Elk's design patent was "'about to issue'" and seeking a declaratory judgment that the "'patent'" was invalid and not infringed. *Id.* Several weeks later, the PTO issued Elk's design patent. On the day that the patent issued, Elk filed its own action against GAF alleging infringement of the design patent. Shortly thereafter, Elk moved to dismiss GAF's earlier filed action for lack of subject matter jurisdiction. The district court granted Elk's motion to dismiss, "holding that there was no actual case or controversy, and thus no subject matter jurisdiction, because the '144 patent had not issued when the suit was commenced." *Id.*

The Federal Circuit affirmed. The court of appeals began by acknowledging that, "when GAF commenced the declaratory judgment action it had a reasonable apprehension that it would be sued for patent infringement." *Id.* at 481. Nevertheless, relying upon *Spectronics*, the Federal Circuit held "*that a threat is not sufficient to create a case or controversy unless it is made with respect to a patent that has issued before a complaint is filed.*" *Id.* at 482 (emphasis added). As

in *Spectronics*, the court of appeals reasoned that it would be impossible to determine whether GAF was an infringer because the “district court did not know with certainty whether a patent would issue or, if so, what legal rights it would confer upon Elk.” *Id.* Moreover, the Federal Circuit concluded that the district court “could not have provided ‘specific relief through a decree of a conclusive character,’ since there was no issued patent for the court to declare ‘invalid’ or ‘not infringed.’” A declaratory judgment of ‘invalidity’ or ‘noninfringement’ with respect to Elk’s pending patent application would have had no legal meaning or effect.” *Id.* (citation omitted).

The same is true here. The ’159 application is currently pending in the PTO. The parties do not know whether a patent will ever issue, nor do they know what claims that patent will contain if it is ever issued, regardless of the state of those proposed claims today. In the absence of any issued claims by which to gauge their actions, plaintiffs cannot establish that they are engaging, or preparing to engage, in *infringing* conduct—a jurisdictional requirement for a declaratory relief action. Plaintiffs’ inability to satisfy this jurisdictional requirement has nothing to do with the particular legal doctrine plaintiffs believe would render any patent issuing from the ’159 application invalid or unenforceable.⁴

⁴ At the October 6 hearing, counsel for Amgen and Immunex contended that Columbia’s covenant was inadequate to eliminate a current case or controversy because it did not cover claims in the ’159 application that are the same as, or substantially identical to, claims in the ’275 patent. In support of this position, counsel argued that, in *Spectronics*, the defendant did not simply grant a covenant not to sue; rather, the defendant made a substantive admission that the declaratory plaintiff did not infringe any claims of the ’366 patent—an admission that would therefore preclude an infringement action on any claim in the pending reissue application that was the same as, or substantially identical to, a claim of the ’366 patent. Ex. A (Tr. at 55:16-21).

This argument finds absolutely no support in the text of the *Spectronics* decision. Nowhere in the decision does the Federal Circuit suggest that the defendant had made a substantive admission that the declaratory plaintiff did not infringe the ’366 patent. Indeed, quite

In addition, as in *GAF Building*, this Court cannot provide “specific relief through a decree of a conclusive character” unless and until the PTO issues a patent based on the ’159 application. A declaratory judgment that a pending patent application is “unenforceable” for prosecution laches has no more legal meaning than a declaratory judgment that a pending patent application is “invalid” or “not infringed.” It is only the *claims* in an *issued* patent that are susceptible to a declaration of unenforceability based on prosecution laches. See *Symbol Technologies, Inc. v. Lemelson Medical*, 277 F.3d 1361, 1363 (Fed. Cir. 2002) (“the equitable doctrine of laches may be applied to bar enforcement of patent *claims* that *issued* after an unreasonable and unexplained delay in prosecution”) (emphasis added); see also *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, No. Civ.02-332-SLR, 2004 WL 1739720, at *33 (D. Del. Aug. 3, 2004) (after considering “whether the patentee unreasonably delayed in prosecuting [specific] claims once filed[,] . . . the court conclude[d] that plaintiffs did not obtain claim 1 of the . . . patent after an unreasonable and unexplained delay in prosecution”). In short, it would be a legal nullity for a court to declare that a proposed claim in a pending patent application is “unenforceable.” See *GAF Building*, 90 F.3d at 482 (“A declaratory judgment of ‘invalidity’ or ‘noninfringement’ with respect to Elk’s pending patent application would have had no legal meaning or effect.”).⁵

to the contrary, the opinion clearly states: “Neither party disputes that, under ordinary circumstances, Spectronics’ production of DYGL0-12 would potentially infringe the claims of the ’366 patent.” 940 F.2d at 636. Moreover, the Federal Circuit described the defendant’s “Statement of Non Liability” as a “covenant not to sue,” not as a substantive admission of non-infringement. *Id.* at 633.

⁵ See also *Technimark, Inc. v. Crellin, Inc.*, 14 F. Supp. 2d 762, 764-65 (M.D.N.C. 1998) (“Defendants argue next that a judgment of invalidity will have ‘legal significance concerning several patent applications Plaintiff currently has pending in the PTO that are related to the ’677 patent.’ . . . Even if such patent applications were pending, the court would not issue a

III. CONCLUSION

For the foregoing reasons, and those discussed in Columbia's previously filed briefs in support of its motion to dismiss, Columbia respectfully submits that there is no actual case or controversy sufficient to permit the exercise of subject matter jurisdiction over any of plaintiffs' declaratory judgment claims, including those alleging unenforceability based on prosecution laches. Accordingly, Columbia requests that the Court grant the motion to dismiss for lack of subject matter jurisdiction.

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Respectfully submitted,

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declaratory judgment merely to influence or guide the PTO's determination. 'It is not the role of federal courts to directly supervise the functions of the patent office by rendering advisory opinions as to the correctness of patent awards.'") (citing *Bioxy, Inc. v. Birko Corp.*, 935 F. Supp. 737, 741 (E.D.N.C. 1996)).